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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/920,953

08/02/2001

Molian Deng

38-21(52114)B

9080

27161

7590

03/16/2006

MONSANTO COMPANY

800 N. LINDBERGH BLVD.

ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA)

ST. LOUIS, MO 63167

EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,953

Applicant(s)

DENG ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/2/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed September 1, 2004 and the Examiner's Answer mailed April 20, 2005). The instant application does not disclose a specific, substantial, and credible utility for SEQ ID NO: 2 or for any polypeptide that is encoded by SEQ ID NO: 2. Applicants' arguments (Brief, pages 4-14) are not convincing. Applicants argue that SEQ ID NO: 2 may be used in the following ways and that each of these meets the requirement for utility under 35 USC § 101:

- (a) in the identification of polymorphisms, (Brief, page 5, last full paragraph),
- (b) to measure the level of or presence of *Chlorella* in a sample (Brief, page 5, last full paragraph and paragraph bridging pages 6-7),
- (c) to measure levels of mRNA (Brief, page 6, first full paragraph),
- (d) as a molecular marker (Brief, page 6, first full paragraph),
- (e) to isolate promoters and transcriptional regulatory elements (Brief, page 6, first full paragraph),
- (f) in cosuppression or antisense expression constructs (Brief, page 6, first full paragraph),
- (g) as probes for other molecules (Brief, page 8, second full paragraph),
- (h) as a source of primers (Brief, page 8, second full paragraph), and
- (i) to find a promoter by doing a chromosome walk starting from the chromosomal locus of SEQ ID NO: 2 (Brief, paragraph bridging pages 8-9).

None of these utilities is specific or substantial. The general assertions in connection with utility can be made for virtually any naturally occurring DNA. Since those DNAs originate in organisms, any such DNA may be used to determine the presence, absence, or level of the organism present in a sample, the

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presence or absence of polymorphisms, the levels of mRNA, or as probes. (See also, Revised Interim Utility Guidelines Training Materials, <http://www.uspto.gov/web/menu/utility.pdf> at pages 5-8.) Since DNAs are present in chromosomes, any naturally occurring DNA can be used as a starting point for a chromosome walk to discover some other region of DNA that may or may not be useful within the meaning of 35 USC § 101 (*e.g.*, a promoter). Likewise, any DNA may be used as a primer (to produce more of itself) or as a molecular marker or probe (to detect sequences like itself). Without a teaching or disclosure as to the significance of a particular DNA, as compared to any DNA in general, the instant claims do not meet the requirement for patentable utility under 35 USC § 101. The U.S. Supreme Court in *Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966) stated,

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit [383 U.S. 519, 535] exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

This is the status of the claimed invention. Applicants also make analogies between the claimed nucleic acids and apparatus inventions (*i.e.*, golf clubs, microscopes, and gas chromatographs). None of these analogies is convincing because: the use of golf clubs is clear – to hit golf balls; the use for microscopes is clear – to magnify images; and the use of gas chromatographs is clear – chemical analysis. In contrast, the use of SEQ ID NO: 2 is not clear, disclosed, readily apparent, well-established, specific, or substantial. The U.S. Supreme Court in *Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966) made it clear that to meet the utility requirement under 35 USC § 101, an invention must be useful in its currently available form.

"This is not to say that we mean to disparage the importance of contributions to the fund of scientific information [383 U.S. 519, 536] short of the invention of something

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"useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It's not a reward for the search, but compensation for its successful conclusion."

The instant application provides only a starting point for the hunt. It does not reach a successful conclusion.

Applicants argue for the separate patentability of claims 6-10 (Brief, pages 10-12) which claims are drawn to transformed cells. Applicants argue that SEQ ID NO: 2 when introduced into cells can be used to follow plants through a breeding program. The arguments hereinabove in connection with a lack of specific utility is incorporated here. Virtually any DNA (providing that its sequence is unique compared to sequences that occur naturally within the cells to be transformed) can serve the purpose of genetically tracking transformed cells or their progeny through a "breeding program". Thus, the use of SEQ ID NO: 2 as a marker is not a specific utility.

Applicants' arguments (February 1, 2006, pages 5-9) are not convincing. Applicants argue that SEQ ID NO: 2 encodes 60S Ribosomal Protein L10. This is not disputed. However, applicants confuse the identification of a function of a protein with a patentable utility under 35 U.S.C. § 101. In all of applicants' arguments, not a single specific, substantial, and credible utility is disclosed. Neither is a specific, substantial, and credible utility disclosed in the application, nor would one of skill in the art find a patentable utility to be readily apparent given the disclosure in the application and what was known in the art as of the effective filing date of the instant application.

Claims 1-4 and 6-15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussions under the rejection under 35 USC § 101 is incorporated here. Since the claimed invention lacks utility under 35 USC § 101, the instant application does not teach how to use the invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.


OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
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3/15/06